NO. 22-13218

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

VIRGINIA REDDING
Plaintiff-Appellee,

v.

COLOPLAST CORP.,
Defendant-Appellant.

On Appeal from the United States District Court for
the Middle District of Florida, No. 6:19-cv-01857-CEM-GJK
Hon. Carlos E. Mendoza U.S. District Judge

APPELLANT'S INITIAL BRIEF

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January 6, 2023

CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and 11th Circuit Local Rule 26.1-1, Defendant-Appellant Coloplast Corp., hereby files its certificate of interested persons and corporate disclosure statement as follows:

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* * * *

Defendant/Appellant Coloplast Corp., a privately held corporation, is a wholly owned subsidiary of Coloplast A/S, a publicly held foreign corporation (COLO-B, Nasdaq Copenhagen).

/s/ *Val Leppert*
Val Leppert

STATEMENT REGARDING ORAL ARGUMENT

Coloplast believes that oral argument would assist the Court in deciding this case. This appeal raises critical and often-recurring issues concerning the application of Florida's statute of limitations in medical-device product-liability cases. There is also a voluminous record following an almost two-week jury trial involving scientific and medical testimony. Oral argument would enhance the Court's understanding of the legal and medical concepts at issue in this case.

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INTRODUCTION

In this product-liability case, Plaintiff Virginia Redding alleged that pelvic-mesh medical devices sold by Coloplast were defectively designed because the devices eroded inside of her body and thereby caused infections, pain, and bad odor. A jury in the Middle District of Florida agreed with Plaintiff and awarded her $2.5 million in damages.

On appeal, Coloplast challenges the district court's denial of its motion for judgment as a matter of law based on Florida's four-year statute of limitations for product-liability cases. The record is undisputed that Plaintiff was diagnosed with a mesh erosion in December 2009, more than four years before she filed suit on September 28, 2014. Plaintiff's doctor told her in December 2009 that the mesh device had eroded and was causing her pain, infection, and odor. Plaintiff thus had actual knowledge of the condition that is the premise of her lawsuit. She further confirmed at trial that the infection and pain that she experienced before the September 28, 2010 cut-off date were "the same complaints" she experienced in 2014 when she filed this case. And beyond that, Plaintiff even understood back in December 2009 that "there was something wrong" with the mesh device.

Against this record, there is no question that Plaintiff's claim is time-barred. Actual knowledge of the relevant injury *and* its link to a product easily triggers Florida's statute of limitations in product liability cases. All that is required is "some evidence of causal relationship" between the injury and the product, *Carter v. Brown & Williamson Tobacco Corp.*, 778 So. 2d 932, 934 (Fla. 2000), to put the plaintiff on notice of a "possible invasion of [her] legal rights," *Univ. of Miami v. Bogorff*, 583 So. 2d 1000, 1004 (Fla. 1991).

The district court denied Coloplast's motion based on its reading of this Court's decision in *Eghnayem v. Boston Scientific Corp.*, 873 F.3d 1304 (11th Cir. 2017). But that was error. Unlike the plaintiff in *Eghnayem,* Plaintiff here had knowledge of the relevant condition (erosion), its source (the mesh product), her symptoms (pain, odor, discharge), *and* that "something was wrong" with the mesh product more than four years before she sued. So unlike in *Eghnayem*, there was no question of fact as to whether Plaintiff reasonably attributed her problem to the surgical procedure as opposed to the device. And, again unlike *Eghnayem*, there was no need for Coloplast to show that Plaintiff's symptoms were "distinct" from normal post-surgery complications to

independently put her on notice of a potential claim. She was diagnosed with a condition that is linked only to the product, and she believed that something was wrong with the product before the cut-off date. That's more than enough notice to start the limitations period in Florida.

The district court's contrary conclusion, based on its overbroad reading of *Eghnayem*, is inconsistent with Florida law. If the Court has any doubt about that, it should certify a question to the Florida Supreme Court. After all, the Florida Supreme Court has never imposed a "distinct injury" requirement to commence the limitations period in a product-liability case, let alone in a case where the plaintiff had actual knowledge of the relevant injury *and* its causal connection to the product. This Court should not adopt the district court's expansion of Florida law without first allowing the Florida Supreme Court to weigh in.

STATEMENT OF THE ISSUE

Whether the district court erred in denying judgment as a matter of law in favor of Coloplast based on Florida's statute of limitations.

JURISDICTIONAL STATEMENT

The district court had diversity jurisdiction over this case under 28 U.S.C. § 1332 because the parties are citizens of different states and the amount in controversy exceeds $75,000. This Court has jurisdiction to

address this appeal under 28 U.S.C. § 1291 because it arises from a final judgment signed by the district court judge on August 25, 2022. Dkt. No. 413, at 2.

STATEMENT OF THE CASE

A. Factual background

While using the restroom one day in 2008, Plaintiff Virginia Redding felt "something coming out of [her] like an intestine or something." Dkt. No. 342 (Trial Tr., Vol. 5, at 523:1–4). Not knowing what it was, Plaintiff "kind of pushed it back up, but it came back down again." *Id.* at 523:5–7. Plaintiff consulted her doctor about the issue but was assured that it was "something that happens" following childbirth. *Id.* at 523:6–9. Accordingly, she "assumed that it would maybe kind of go back up on its own." *Id.* at 523:9–10.

But the issue did not resolve itself. *Id.* at 523:11–12. As the bulge continued to grow in 2009, it also became more painful. *Id.* at 523:13–16. During that time, Plaintiff also dealt with stress urinary incontinence, causing her to wear pads and panty liners. *Id.* at 524:16–22. After the pain became "unbearable," Plaintiff decided to consult a new doctor. *Id.* at 523:19–20; 525:1–2. Plaintiff first saw her primary care provider but was ultimately referred to Dr. Robert Weaver.

On November 6, 2009, Dr. Weaver diagnosed Plaintiff with pelvic organ prolapse, Dkt. No. 351 (Trial Tr., Vol. 7, at 982:16–983:16), a condition where increased pressure on the pelvic floor results in sagging and loss of support, Dkt. No. 336 (Trial Tr., Vol. 3, at 324:3–17). Pelvic organ prolapse, often the result of childbirth, can cause the bladder, uterus, or rectum to fall. *Id.* at 324:3–22. Dr. Weaver also diagnosed Plaintiff with bladder neck hypermobility, which he believed could possibly be causing "stress [urinary] incontinence," an involuntary leaking of urine. Dkt. No. 351 (Trial Tr., Vol. 7, at 983:10–16).

Dr. Weaver walked Plaintiff through possible treatment options, including a hysterectomy and surgically implanting a mesh sling. *Id.* at 525:21–526:15. Because Plaintiff "didn't feel comfortable with having a hysterectomy," she opted for the mesh device. *Id.* at 526:10–12. On December 15, 2009, Plaintiff had two of Coloplast's mesh products surgically implanted: NovaSilk™ and Supris®. Dkt. No. 342 (Trial Tr., Vol. 5, at 517:22–518:1). NovaSilk is a polypropylene mesh that provides "lost support" to the vaginal wall, Dkt. No. 353 (Trial Tr., Vol. 8, at 988:9–989:1), whereas Supris is a polypropylene mesh sling that provides

support to the bladder neck to prevent urine leakage during stress maneuvers, Dkt. No. 336 (Trial Tr., Vol. 3, at 360:20–361:17).

Before surgery, Dr. Weaver informed Plaintiff "about a risk of [mesh] erosion," Dkt. No. 342 (Trial Tr., Vol. 5, at 526:19–21), where an inflammatory reaction with tissue causes an infection and can lead to the material becoming visible in the vagina or even piercing vaginal tissue. Dkt. No. 379 (Trial Tr., Vol. 13, at 1511:14–23). Despite those risks, Plaintiff chose to go forward with the surgery because she "wanted to have more of a – much more of a comfortable life than what [she] was" having. Dkt. No. 342 (Trial Tr., Vol. 5, at 527:8–11).

Following her surgery on December 15, 2009, Plaintiff "experienced some pain and some bleeding." *Id.* at 527:18–23. Over the next six months, Plaintiff had five follow-ups with Dr. Weaver concerning her post-surgery symptoms. During those follow-ups, Plaintiff was repeatedly told that a mesh erosion was causing her symptoms.

For instance, during her December 28, 2009 follow-up with Dr. Weaver, Plaintiff complained of a distinct odor and sharp pain in the bottom of her stomach that made her "vagina area ache[ ] like a

toothache." *Id.* at 530:1–13. At that time, Dr. Weaver told Plaintiff that she "had an erosion of the mesh." *Id.* at 556:3–5.

Plaintiff "understood as of that date, December 28, 2009, that there was an erosion of the mesh occurring in [her] vagina," and "that it was infected and creating an odor." *Id.* at 556:9–15. She was told again on January 13, 2010, *id.* at 557:21–23, again on February 10, 2010, *id.* at 558:2–10, and again on March 18, 2010, *id.* at 558:11–13. During that fourth visit, Plaintiff complained that her bulge was returning, causing her discomfort while standing. *Id.* at 558:19–21. During Plaintiff's fifth and final follow-up with Dr. Weaver on May 10, 2010, she complained that she was having trouble emptying her bladder. *Id.* at 559:17–560:2.

In light of what Plaintiff was told about her mesh erosion and the pain she was experiencing as a result, Plaintiff also understood in December 2009 that "there was something wrong" with the mesh device. *Id.* at 530:16–22.

Following her May 2010 visit, Plaintiff did not see Dr. Weaver or any other doctor about the issue until 2014, Dkt. No. 342 (Trial Tr., Vol. 5, at 562:17–23), even though Plaintiff continued to experience erosion, infection, pain, and incontinence, *id.* at 563:10–13. During this time,

Plaintiff took no steps to investigate the cause of her symptoms: she did not do any research, *id.* at 561:3–7, did not return to Dr. Weaver, *id.* at 561:8–13, and did not seek a second opinion from an OBGYN, *id.* That's understandable—after all, Plaintiff had already been told by Dr. Weaver on five occasions that a mesh erosion was causing her symptoms.

More than four years later, on June 12, 2014, Plaintiff began treatment with Dr. Stephen McCarus. Dkt. No. 344 (Trial Tr., Vol 6, at 622:12–17). Plaintiff came to Dr. McCarus complaining of vaginal bleeding and pelvic pain. *Id.* at 622:15–17. Dr. McCarus diagnosed Plaintiff with organ prolapse and mesh erosion, *Id.* at 623:16–624:1, and performed two mesh removal surgeries. Dkt. No. 342 (Trial Tr., Vol. 5, at 536:5–19). Notably, the complaints Plaintiff reported to Dr. McCarus in June 2014 were "the same complaints" she had in December 2009. *Id.* at 563:20–24; *compare* Dkt. No. 342 (Trial Tr., Vol. 5, at 527:18–21; 533:18–534:4, 554:20–556:15, 557:21–558:1, 558:7–559:3, 559:19–22) (describing symptoms during visits with Dr. Weaver) *with id.* at 521:3–8, 532:2–5, 534:7–8; 535:21–536:4, 559:17–22; 563:10–24 (describing symptoms after stopping treatment with Dr. Weaver).

Shortly after receiving Dr. McCarus's diagnosis of mesh erosion in the summer of 2014—her sixth diagnosis of mesh erosion going back to December 2009—Plaintiff finally brought suit on September 28, 2014.

B. Proceedings below

1. Plaintiff's case

Plaintiff initially filed suit against Coloplast in the United States District Court for the Southern District of West Virginia as part of the mesh MDL, but the case was later transferred to the Middle District of Florida. Dkt. No. 3, at 1–2.

Plaintiff alleged that Coloplast's mesh was defectively designed and that Coloplast failed to provide adequate warnings for its products. Dkt. No. 1, at 5. The design claim asserted that Coloplast's products used polypropylene mesh, which—according to Plaintiff—can cause "painful recurrent erosions and associated intractable pain." Dkt. No. 66-13, at 16–17. As explained more below, much of Plaintiff's claim was that Coloplast's mesh devices erode too often when implanted into the female pelvic area and thus the risks of the design outweigh its benefits.

2. Coloplast's motion for summary judgment

Following discovery, Coloplast moved for summary judgment because Plaintiff's suit was time-barred under Florida law. Dkt. No. 53, at 2. Under Florida Statute § 95.031(2)(B), a product-liability suit must be filed within four years "from the date that the facts giving rise to the cause of action were discovered, or should have been discovered with the exercise of due diligence." Fla. Stat. § 95.031(2)(B). Coloplast explained that Plaintiff's diagnosis of mesh erosion, coupled with Dr. Weaver telling Plaintiff that the erosion was causing her symptoms, was enough to put her on "notice, through the exercise of reasonable diligence, of the possible invasion of [her] legal rights." *Bogorff*, 583 So. 2d at 1004.

After noting that Coloplast's statute of limitations argument "ma[de] a certain amount of logical sense," the district court nonetheless denied the motion, concluding that this Court's precedent "compel[led] the opposite conclusion." Dkt. No. 110, at 5. The district court found that the facts of *Eghnayem v. Boston Scientific Corp.*, 873 F.3d 1304 (11th Cir. 2017), were "strikingly similar to the facts" Plaintiff presented. Dkt. No. 110, at 7. In *Eghnayem*, this Court rejected a statute of limitations defense involving a claim of defective vaginal mesh. 873 F.3d at 1310–

11. The district court further relied on this Court's unpublished opinion from *In re Mentor*, 748 F. App'x 212 (11th Cir. 2018), which also involved a statute of limitations defense for a vaginal mesh suit.

3. Trial evidence

Trial proceeded over the course of nine days. In opening statement, Plaintiff's counsel asserted that Coloplast was aware of "high rates of erosions" in its mesh products, Dkt. No. 332 (Trial Tr., Vol. 2, at 171, 173, 180), that Plaintiff experienced multiple erosions of her mesh, *id.* at 185, and that she has suffered significant pain and discomfort as a result, *see, e.g.*, *id.* at 180, 185.

Plaintiff presented several witnesses, starting with Dr. Bruce Rosenzweig, her general causation expert. Dr. Rosenzweig discussed the potential complications associated with mesh erosions, such as pain in various areas of the body, especially during certain activities like urination or sexual intercourse. Dkt. No. 336 (Trial Tr., Vol. 3, at 345). Dr. Rosenzweig defined "erosion of mesh" as when "mesh destroys the tissue either of the vagina . . . or it does the same to the tissue of the bladder or the urethra," leading to pain and infection. *Id.* at 407:8–14. Because of the risk of mesh erosion and its consequences, Dr. Rosenzweig

posited that NovaSilk "create[s] more serious long-term complications than it actually corrects." *Id.* at 328:1–4. And, referencing Florida's standard for determining a design defect in prescription-device cases, Dr. Rosenzweig opined that the risks of Coloplast's mesh devices "outweigh the benefits." Dkt. No. 336 (Trial Tr., Vol. 3, at 390).

Next, Plaintiff took the witness stand. As previewed above, she testified that she chose pelvic floor reconstruction surgery with two mesh devices to address her organ prolapse and incontinence. *See supra*, 4-6. Following her mesh implantation surgery, Plaintiff began to experience some troubling symptoms, including a foul odor that prevented her from being with friends and a sharp pain that ran from the bottom of her stomach to her vagina. *Id.* at 530:1–13. Plaintiff testified that she told Dr. Weaver about these symptoms during her December 28, 2009 follow-up, roughly two weeks after her surgery. *Id.* at 530:1–15. Dr. Weaver examined Plaintiff and diagnosed her with "a small area of erosion." *Id.* at 531:9–17.

As explained earlier, Dr. Weaver repeated the diagnosis of mesh erosion five times between December 28, 2009 and May 2010. *See supra*, 6-7. And based on her discussions with Dr. Weaver, Plaintiff "understood

as of that date, December 28, 2009, that there was an erosion of the mesh occurring in [her] vagina," and "that it was infected and creating an odor." *Id.* at 556:9–15.

On direct examination, Plaintiff's counsel asked Plaintiff whether, on December 28, 2009, she "believed that the products that had been implanted you in [sic] were unsafe." Plaintiff responded, "I thought something was wrong with it, that something was just not – I don't know. Something was wrong and I – I don't know." *Id.* at 530:16–22. When pressed by her counsel, Plaintiff said that while she knew something was wrong, she did not know exactly *what* was wrong. *Id.* at 531:6–8.

Plaintiff also testified about seeing Dr. McCarus in the summer of 2014, shortly before filing this lawsuit in September 2014. On cross examination, Plaintiff agreed that "the *same complaints* that [she] presented to Dr. McCarus with [in June 2014] of the pain, the odor, the leaking of urine, [her] bladder starting to fall out again, those were the complaints [she] had when she saw Dr. Weaver in May of 2010." *Id.* at 563:20–24 (emphases added).

Plaintiff then called Dr. McCarus as a witness. He testified about diagnosing Plaintiff with multiple erosions in 2014 and performing two

mesh removal surgeries. *See, e.g.*, Dkt. No. 344 (Trial Tr., Vol. 6, at 626-27, 629, 631, 636, 639-40, 642).

After Dr. McCarus, Plaintiff called Dr. Lennox Hoyte, a paid expert who routinely testifies for plaintiffs in mesh litigation. Dkt. No. 351 (Trial Tr., Vol. 7, at 785). Based on his interpretation of Dr. Weaver's medical records, Dr. Hoyte claimed that Plaintiff was "asymptomatic" during her 2009 and 2010 visits, *id.* at 803:16–20, and only began displaying symptoms of mesh erosion in 2014, *id.* at 814:4–14. Dr. Hoyte further opined that Plaintiff's mesh erosion in 2009/2010 was a distinct and separate erosion from the erosion Plaintiff experienced by 2014. *Id.* at 816, 838:21-839:3.

Plaintiff's last medical witness was Dr. Weaver. While he had no independent recollection of Plaintiff, Dr. Weaver testified based on his records about his treatment of Plaintiff, including warning Plaintiff about the risk of mesh erosion, performing the implant surgery, and then diagnosing Plaintiff with mesh erosion multiple times. But Dr. Weaver also claimed that he was not overly concerned about her erosion because "it never changed," "[i]t was never bothering anything," it was "tiny," and he had seen erosions one-hundred times bigger. Dkt. No. 353 (Trial Tr.,

Vol. 8, at 1059:14–22). He further testified that he believed the erosion to be "asymptomatic" at the first two post-operative visits because his medical records did not indicate that Plaintiff reported pain at that time. *Id.* at 1012. But Plaintiff did report pain and discomfort on her third visit on March 18, 2010. *Id.* at 1023. Dr. Weaver's records did not indicate, however, that Plaintiff reported pain on her last visit on May 10, 2010. *Id.* at 1025.

On cross-examination, Dr Weaver acknowledged that "all [he had] to go on are the written words on [his] medical records." Dkt. No. 353 (Trial Tr., Vol. 8, at 1037). So "if [Plaintiff now] says she had pain at a certain time and it's not in [his] record," he would not have "any way to figure out which is right." Dkt. No. 353 (Trial Tr., Vol. 8, at 1037).

4. Motion for judgment as a matter of law

At the end of Plaintiff's case, Coloplast moved for judgment as a matter of law under Federal Rule of Civil Procedure 50(a), Dkt. No. 360, explaining that Plaintiff's cause of action accrued before September 28, 2010—*i.e.,* more than four years before she sued. In her memorandum in opposition, Plaintiff argued that she "had no reason to believe she had a lawsuit in 2009-2010." Dkt. No. 383, at 1. She contended that the

symptoms she presented to Dr. Weaver—"a tiny erosion," "plus some drainage and an odor"—were not "sufficiently dramatic" to trigger the statute of limitations as a matter of Florida law. *Id.* at 2–3. Plaintiff also argued that knowledge of an injury connected to a product is not enough for the statute to accrue; instead, Plaintiff claimed Coloplast needed to prove that Plaintiff knew that the mesh was defective. *Id.* at 3–4. The district court deferred its ruling.

5. Verdict and post-trial proceedings

The jury ultimately found that Plaintiff's claim was not barred by the statute of limitations. Dkt. No. 393 (Trial Tr., Vol. 17, at 29:10–11). The jury also found for Plaintiff on several of her substantive claims and awarded her $2,500,000 in compensatory damages. *Id.* at 30:15. After the trial, Coloplast timely renewed its motion for judgment as a matter of law under Federal Rule of Procedure 50(b). Dkt. No. 410.

Roughly three months later, the district court denied Coloplast's original motion under Rule 50(a), again relying on *Eghnayem* and stating that "the trial record contain[ed] sufficient evidence for a reasonable jury to find that Plaintiff was not aware of an injury distinct in some way from conditions naturally to be expected from her implantation and that such

injury was causally connected to Defendant's products until after September 28, 2010." Dkt. No. 405, at 7 (quotation omitted). The district court then also denied Coloplast's Rule 50(b) motion. Dkt. No. 413.

STANDARD OF REVIEW

This Court reviews the denial of a "motion for judgment as a matter of law *de novo*, considering only the evidence that may properly be considered and the reasonable inferences drawn from it in the light most favorable to the nonmoving party." *Rossbach v. City of Miami*, 371 F.3d 1354, 1356 (11th Cir. 2004).

SUMMARY OF THE ARGUMENT

I.A. Plaintiff waited too long to file her case. More than four years before she sued, Plaintiff was diagnosed with pelvic pain caused by an erosion of the mesh device—the condition that is the premise of her lawsuit. Plaintiff also admitted that several months before the September 28, 2010 cut-off date, she already experienced the same type of infection and pain for which she sought and recovered damages in this case. Even further, Plaintiff thought that "something was wrong" with the mesh product more than four years before she filed her case.

By any reasonable view of this record, Plaintiff's case is time-barred under Florida's four-year statute of limitations. In a product-liability

case like this one, the statute undoubtedly begins to run when the claimant is aware of her injury and a possible causal link to the defendant's product. Plaintiff here was told by a doctor that her pain was caused by a mesh erosion—a diagnosis that literally links the product to the injury and led Plaintiff to conclude that "something was wrong" with the product, *not* with the surgical procedure. Florida law requires nothing further for the limitations period to commence.

B. The district court denied Coloplast's motion based on its misapplication of this Court's decision in *Eghnayem v. Boston Scientific Corp.*, 873 F.3d 1304 (11th Cir. 2017). Unlike the plaintiff in *Eghnayem,* Plaintiff here had knowledge of the relevant condition (erosion), its source (the mesh product), her symptoms (pain, odor, discharge), *and* that "something was wrong" with the mesh product more than four years before she sued. So unlike in *Eghnayem*, there was no reasonable dispute as to whether Plaintiff attributed her complaints to the device as opposed to the surgical procedure.

Again unlike *Eghnayem*, this case simply does not turn on whether Plaintiff's symptoms were "distinct" from normal post-surgery complications or "sufficiently dramatic" to independently put her on

notice of a potential claim against Coloplast. She was diagnosed with a condition that is linked only to the product, which led her to believe that something was wrong with the product more than four years before she filed suit. Actual knowledge of an injury and its link to the product easily triggers the limitations period in a product-liability case. A "distinct injury" was thus not necessary to provide notice to Plaintiff. The district court's contrary conclusion, based on its overbroad reading of *Eghnayem*, renders Florida's statute of limitations virtually non-existent.

C. Plaintiff's other counterarguments are also unpersuasive. In opposing Coloplast's Rule 50 motion, Plaintiff argued that the mesh erosion was "tiny" and that her symptoms before the September 28, 2010 cut-off date could have just been "common side effect[s] of the surgery" and thus were not sufficient to alert her of a defect in the mesh. Each of these points misses the mark. To begin, Plaintiff testified that she had significant complaints before the cut-off date and that these complaints were "the same complaints" she had in 2014 when she filed this lawsuit. But in any event, Florida' statute of limitations is not postponed just because the full extent of her damages is not yet apparent. The clock

begins to run when the plaintiff has actual or constructive notice of the *first* invasion of her legal rights.

Plaintiff also misfires with her discussion of "common side effects." She was diagnosed with a mesh erosion—the condition at issue in this lawsuit—and she understood that "something was wrong" with the mesh product. So even if Plaintiff believed that mesh erosions are "common side effects," she was still on notice of the facts giving rise to this lawsuit. Plaintiff's own theory was that mesh devices are defectively designed because mesh erosions are a side effect that is *too common*.

Equally unavailing is Plaintiff's suggestion that she did not have sufficient notice of a defect in the product. No Florida appellate court has ever required notice of a product defect for the limitations period to trigger. Instead, the Florida Supreme Court has required only "some evidence of causal relationship" between the injury and the product, *Brown & Williamson*, 778 So. 2d at 934, to put the plaintiff on notice of a "possible invasion of [her] legal rights," *Bogorff*, 583 So. 2d at 1004.

But in any event, Plaintiff here was diagnosed with a mesh erosion and understood the link between her injury and the product. And she thought "something was wrong" with the product in December 2009. So

even assuming notice of a possible defect were required under Florida law, Plaintiff's claim would still be time-barred.

II. If this Court has any inclination to affirm the judgment based on the district court's understanding of Florida law, it should allow the Florida Supreme Court to weigh in first. As explained in this brief, the Florida Supreme Court has never required a "distinct injury" in a product-liability case, let alone in a case with an actual diagnosis that links the product to the injury. Nor has the Florida Supreme Court ever required notice of a product defect. But the district court and Plaintiff read this Court's decision in *Eghnayem* to always require both elements to trigger Florida's statute of limitations. The Florida Supreme Court has not had a chance to address these issues in a medical device case. If *Eghnayem* really means what the district court and Plaintiff think, then it's high time to ask the Florida Supreme Court whether it agrees with such novel expansions of Florida law.

ARGUMENT

I. The District Court Erred In Denying Judgment As A Matter Of Law In Favor Of Coloplast

A. Florida's statute of limitations bars Plaintiff's claim as a matter of law

1. The Florida Legislature has determined that a plaintiff has four years to commence a product-liability suit. Fla. Stat. § 95.031(2)(b). The Legislature further directed that the four-year period begins to run "from the date that the facts giving rise to the cause of action were discovered, or should have been discovered with the exercise of due diligence." *Id.*

Applying the Legislature's directive, the Supreme Court of Florida has held that an action for products liability accrues when a plaintiff's injuries "manifest themselves . . . in a way which supplies some evidence of a causal relationship to the manufactured product." *Carter v. Brown & Williamson Tobacco Corp.*, 778 So. 2d 932, 934 (Fla. 2000). "The knowledge required to commence the limitation period, however, does not rise to that of legal certainty." *Univ. of Miami v. Bogorff*, 583 So. 2d 1000, 1004 (Fla. 1991), *holding modified on other grounds by Tanner v. Hartog*, 618 So. 2d 177 (Fla. 1993). Rather, "[p]laintiffs need only have notice, through the exercise of reasonable diligence, of the *possible* invasion of their legal rights." *Id.* (emphasis added).

2. Here, there is no legitimate question that Plaintiff's claim accrued more than four years before she filed this lawsuit on September 28, 2014. Plaintiff had ample of notice of the "possible invasion of [her] legal rights," *Bogorff*, 583 So. 2d at 1004, several months before the September 28, 2010 cut-off date. As discussed below, the evidence at trial was undisputed that before September 28, 2010, Plaintiff already (a) knew she had suffered a mesh erosion, the condition for which she is suing in this lawsuit, (b) experienced the same kind of pain for which she recovered $2.5 million in damages at trial, and (c) she understood that "something was wrong" with the mesh product.

a. Shortly following her mesh implantation surgery on December 15, 2009, Plaintiff began experiencing symptoms of mesh erosion, including a distinct odor and sharp pain in the bottom of her stomach that made her "vagina area ache[ ] like a toothache." *Id.* at 530:1–13. As she confirmed at trial, Plaintiff understood that these symptoms were not typical post-surgery complications, but instead were a result of a "mesh erosion:"

> Q. And when he examined you [on December 28, 2009] *he told you that you had an erosion of the mesh*, correct?
>
> A. *Yes.*

> Q. And he told you that that smell that you were experiencing was because you were infected in that area, correct?
>
> A. Yes.
>
> Q. And you *understood* as of that date, December 28, 2009, *that there was an erosion of the mesh* occurring in your vagina, correct?
>
> A. *Yes.*
>
> Q. And you *understood that it was infected* and creating an odor, correct?
>
> A. *Yes.*

Dkt. No. 342 (Trial Tr., Vol. 5, at 556:3–15 (emphases added)). Based on this alone, Plaintiff had actual knowledge of her mesh erosion by December 28, 2009. She was *diagnosed* with the condition (infection and pain caused by an erosion) that it is the subject of this lawsuit, and her doctor specifically pointed to the product ("mesh") as the source of her condition.

The Florida Supreme Court has repeatedly held that a diagnosis of the relevant injury, coupled with "some evidence of causal connection" to the product, commences the limitations period in product-liability cases. *Brown & Williamson*, 778 So. 2d at 934; *American Optical Corp. v. Spiewak*, 73 So. 3d 120, 127 (Fla. 2011) (diagnosis of asbestos-related

diseases was "the event that triggered Florida's statute of limitations" in asbestos-liability lawsuit) (emphasis omitted); *Bogorff*, 583 So. 2d at 1004 (holding in prescription-drug case that awareness of injury and of "the possible involvement" of the drug "is sufficient for accrual of the[ ] cause of action.").

b. Plaintiff's trial testimony further confirmed that before the limitations cut-off on September 28, 2010, she already experienced the same symptoms and pain for which she recovered damages in this lawsuit. Plaintiff explained that the infection she "still get[s] . . . today" is the same type of infection Dr. Weaver diagnosed in May 2010. Dkt. No. 342 (Trial Tr., Vol. 5, at 560:25–561:1). And as the following exchange demonstrates, Plaintiff already suffered from "the same complaints" in May 2010 that became the basis of her lawsuit in September 2014:

> Q. Now, the *same complaints* that you presented to Dr. McCarus with [in June 2014] of the pain, the odor, the leaking of urine, your bladder starting to fall out again, those were the complaints you had when you saw Dr. Weaver in May of 2010, correct?
>
> A. Yes.

Id. at 563:20–24 (emphases added).

This testimony shows that "the facts giving rise to the cause of action were discovered, or should have been discovered" no later than May 2010. *See* Fla. Stat. § 95.031(2)(b). If Plaintiff's claim did not accrue upon experiencing the same type of symptoms for which she sought damages in this case in May 2010, *after* having been diagnosed with "mesh erosion" in December 2009, then it never accrued. *See Mikhaylov v. Bilzin Sumberg Baena Price & Axelrod LLP*, 346 So. 3d 224, 228 (Fla. Dist. Ct. App. 2022) (holding that plaintiffs' claim "accrued when the Plaintiffs first suffered a concrete loss (*i.e.*, injury) as a proximate cause of Bilzin's malpractice. Not a day later.").

c. Although the Florida Supreme Court has never required such knowledge to trigger the limitations period in a product-liability case, Plaintiff also had notice of a possible defect in the mesh device more than four years before she filed this lawsuit. Plaintiff testified on direct examination that in December 2009 she already thought that "something was wrong" with the mesh device:

> Q. On December 28, 2009 . . . [d]id you have some complaints at that time for Dr. Weaver about how you were feeling?
>
> A. I did.
>
> * * *

> Q. Okay. At that time, *did you believe that the products* that had been implanted you in [sic] *were unsafe*?
>
> A. *I thought something was wrong with it*, that something was just not – I don't know. Something was wrong and I – I don't know.
>
> Q. *But at the time you knew something was wrong?*
>
> A. *Yes.*

Dkt. No. 342 (Trial Tr., Vol. 5, at 530:16–22 (emphases added)).

With this record in mind, Plaintiff had more than just the required "evidence of causal connection" to the product. *Brown & Williamson*, 778 So. 2d at 934. Plaintiff understood that something was wrong with the product, which is an axiomatic example of having "notice . . . of the possible invasion of [one's] legal rights." *Bogorff*, 583 So. 2d at 1004.

Where a plaintiff is aware of an injury from a product *and* of a possible defect in the product, the statute of limitations undoubtedly begins to run. Under any reasonable view of the record, by May 2010 at the latest, "the effects of [mesh erosion] manifested themselves to [Plaintiff] in a way which supplied some evidence of a causal relationship to the [mesh product]." *R.J. Reynolds Tobacco Co. v. Jewett*, 106 So. 3d 465, 469 (Fla. Dist. Ct. App. 2012) (internal quotation marks omitted). Plaintiff's claim is therefore time-barred as a matter of law.

B. The district court misapplied this Court's precedent

As indicated in its denial of summary judgment, the district court's analysis was grounded in its understanding of this Court's decision in *Eghnayem v. Boston Scientific Corp.*, 873 F.3d 1304 (11th Cir. 2017). Concluding that the facts of *Eghnayem* were "strikingly similar" to Plaintiff's claim, the district court felt that it could not "reach a different outcome." Dkt. No. 110, at 7. This belief continued throughout trial, as the district court denied judgment as a matter of law, again citing *Eghnayem*. Dkt. No. 405, at 7. But the facts of Plaintiff's case, especially as further developed at trial, are distinguishable from *Eghnayem*.

A closer examination of *Eghnayem* makes this clear. The defendant in that case argued that it was entitled to judgment as a matter of law because Ms. Eghnayem experienced a new symptom—urinary incontinence—before the limitations cut-off date, and a doctor told her that the incontinence "was related to the mesh repair." *Eghnayem*, 873 F.3d at 1324–25 (internal quotations omitted). This Court disagreed. Explaining that the defendant needed to show "that Eghnayem was aware of a dramatic change in her condition" and "that she knew of the possible involvement of" the vaginal mesh in that change, this Court

concluded that the claim was not time-barred as a matter of law. *Id.* at 1324 (quoting *Bogorff*, 583 So. 2d at 1004) (cleaned up). According to this Court, Ms. Eghnayem's only new symptom following mesh implantation—urinary incontinence—was not so "obviously unusual" to put her on notice, because it was not a "sufficiently distinct symptom from what might have been expected after vaginal surgery." *Id.* After all, urinary incontinence can be a normal side-effect from surgery or from an underlying medical condition rather than an injury stemming from the product. *Id.* And Ms. Eghnayem's statement that "she believed this new symptom was related to the mesh repair" also did not start the clock as a matter of law. *Id.* The phrase "mesh repair" could be reasonably interpreted to refer to Ms. Eghnayem's pelvic-floor reconstruction surgery with a mesh device, as opposed to an erosion of the mesh. *Id.*

But this case is different. More than four years before she filed suit, Plaintiff was diagnosed with a "mesh erosion," the condition that is the premise of this lawsuit, and the same pain and symptoms for which Plaintiff recovered damages in this lawsuit were also already apparent to her before the cut-off date. Plaintiff candidly admitted that she knew "there was an erosion of mesh occurring in [her] vagina" and that she

"understood it was infected and creating an odor." Dkt. No. 342 (Trial Tr., Vol. 5, at 556:9–15). On top of that, Plaintiff here already knew that "something was wrong" with the mesh product. Dkt. No. 342 (Trial Tr., Vol. 5, at 530:16–22). So, unlike in Ms. Eghnayem's case, there is no question of fact here as to whether Plaintiff reasonably attributed her problem to the surgical procedure. Plaintiff made clear on direct examination that she thought something was wrong *with the product*—not the surgical procedure—in December of 2009, which was several months before the cut-off date.[1]

Contrary to the district court's overbroad application of *Eghnayem*, this case does not turn on whether Plaintiff had a "dramatic change in condition" or whether her symptoms were "distinct in some way from

[1] In its statement of fact in *Eghnayem*, this Court noted that Ms. Eghnayem's doctor told her "that she had exposed mesh in her vagina." 873 F.3d at 1311. But this Court did not base its legal analysis on Ms. Eghnayem's mesh exposure; indeed, the exposure is not mentioned once in the Court's statute of limitations analysis. *Id.* at 1323-24. Besides that, a mesh "exposure" occurs when a doctor can merely see the suture or some graft material in the vagina whereas a mesh "erosion" occurs when that suture or graft material pierces a hollow tube, like the urethral tube. Dkt. No. 379 (Trial Tr., Vol. 13, at 1511:14-23). In other words, an erosion is a more severe event than an exposure. And, at any rate, Plaintiff here had more knowledge than Ms. Eghnayem about her condition and its source.

conditions naturally to be expected from the plaintiff's condition." *Eghnayem*, 873 F. 3d at 1323 (quoting *Babush v. Am. Home Prods. Corp.*, 589 So. 2d 1379, 1381 (Fla. Dist. Ct. App. 1991)). Plaintiff here had *actual* knowledge of the relevant condition, its symptoms, and its causal connection in 2009. There was no need for a "dramatic change" or a "distinct injury" to provide additional, independent notice to Plaintiff.

The district court, not recognizing these material differences, stretched *Eghnayem* well past its breaking point. Under the district court's holding, a product liability claim does not accrue when a plaintiff knows they have been injured *and* what injured them. That is not, and has never been, an accurate description of Florida law. *See Brown & Williamson*, 778 So. 2d at 937 (holding in products liability suit that the action accrued when plaintiff's injury manifested itself "in a way which supplies some evidence of [a] causal relationship to the manufactured product") (citation omitted).[2]

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[2] The district court's decision also was influenced by this Court's decision in *In re Mentor Corp. Obtape Transobturator Sling Products Liab. Litig.*, 748 Fed. App'x 212 (11th Cir. 2018). But that case is unpublished and thus non-precedential. 11th Cir. R. 36-2; *United States v. Izurieta*, 710 F.3d 1176, 1179 (11th Cir. 2013). Beyond that, *In re Mentor* is also distinguishable from this case. Unlike Plaintiff here, the

C. Plaintiff's counterarguments miss the mark

In opposing Coloplast's Rule 50 motion, Plaintiff made three arguments for why her claim is not time-barred. First, Plaintiff argued that the injuries she suffered before the cut-off date were too minor to trigger the statute of limitations. Second, Plaintiff claimed that the statute of limitations was triggered only once she had knowledge that the mesh was *defective*—not when she knew the mesh injured her. Finally, Plaintiff postulated that her mesh erosion could have been a routine surgical complication rather than the result of a defect in the mesh product. As explained next, all three arguments lack merit.

1. According to Plaintiff's brief in opposition, the symptoms she presented to Dr. Weaver in 2009 and early 2010 were relatively trivial: "a tiny erosion that 'never changed,' 'was never bothering anything,' and 'was causing no problem.'" Dkt. No. 383 at 6 (quoting Dkt. No. 353 (Trial Tr., Vol. 8, at 1059:16–22)). Relatedly, Plaintiff claimed that "her injuries in 2014 were substantially different from [her] injuries in 2009-10," *Id.*

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plaintiff in *In re Mentor* "never suspected that the ObTape was defective or . . . had caused her injuries," but instead thought she "was just having an allergy to" the implanted mesh. *In re Mentor*, 748 Fed. App'x at 214–15.

at 9. Based on this, Plaintiff argued that her claim did not accrue before September 28, 2010.

This argument fails as a matter of fact and law. During trial, Plaintiff testified under oath that her symptoms before September 28, 2010 were severe. For instance, during her December 28, 2009 follow-up with Dr. Weaver, Plaintiff complained of a distinct odor and a sharp pain in the bottom of her stomach that made her "vagina ache[ ] like a toothache." Dkt. No. 342 (Trial Tr., Vol. 5, at 530:1–13). During later follow-ups, Plaintiff also complained that her bulge was returning, causing her discomfort while standing, and that she was having trouble emptying her bowels. *Id.* at 558:19–560:2.

The evidence also rebuts Plaintiff's suggestion that her "injuries in 2014 were substantially different from [her] injuries in 2009-10," Dkt. No. 383 at 9. Plaintiff conceded under oath that "the *same complaints* that [she] presented to Dr. McCarus with [in June 2014] of the pain, the odor, the leaking of urine, [her] bladder starting to fall out again, . . . were the complaints [she] had when [she] saw Dr. Weaver in May of 2010." Dkt. No. 342 (Trial Tr., Vol. 5, at 563:20–24 (emphases added)).

But in any event, Plaintiff's argument also fails from a legal standpoint. Even assuming her injuries in late 2009/early 2010 were not as severe as they would later become, Florida's statute of limitation began to run when the mesh erosion was first diagnosed in December 2009. Under Florida's "first injury rule," "the running of the statute [of limitations] is not postponed by the fact that the actual or substantial damages do not occur until a later date." *Kipnis v. Bayerische Hypo-Und Vereinsbank, AG*, 202 So. 3d 859, 862 (Fla.), *opinion after certified question answered*, 844 F.3d 944 (11th Cir. 2016). Instead, the statute of limitations begins to run immediately when "an injury, although slight, is sustained in the consequence of [a] wrongful act." *Id.* No matter how much Plaintiff now tries to trivialize her injuries in 2009 and early 2010, she was diagnosed with a mesh erosion and suffered the same type of complaints for which she later brought suit. The limitations period started the first time she became aware of these facts, regardless of whether Plaintiff's injuries became worse over time or whether she experienced additional erosions at a later time.

2. Plaintiff also reasoned that because she did not know that the mesh was defective before September 2010, her claim is not time-barred.

Dkt. No. 383 at 7. But that argument also fails as a matter of law and fact. Legally speaking, a product-liability claim accrues when a plaintiff's injuries "manifest themselves . . . in a way which supplies some evidence of a causal relationship to the manufactured product." *Brown & Williamson*, 778 So. 2d at 932. Nowhere in Florida law is there an additional requirement that a plaintiff must *also* know that a product is defective before the claim accrues. The Florida Supreme Court has examined the statute of limitations in several product liability cases, such as *Bogorff*, *Brown & Williamson*, and *Spiewak,* and none of those cases imposed such a requirement. Nor has any other Florida appellate court ever required knowledge of a defect in the product.

Factually speaking, Plaintiff was diagnosed with the relevant injury (pain caused by an erosion) and was made aware of the link to the product (mesh erosion), which gave Plaintiff plenty of notice "of the possible invasion of [her] legal rights." *Bogorff*, 583 So. 2d at 1004. And she already believed that "something was wrong" with the product. So *even assuming* Florida law required it, Plaintiff had notice of a possible defect in the product.

3. Finally, Plaintiff argued that her symptoms caused by a mesh erosion in late 2009/early 2010 were "common side effects of the surgery," Dkt. No. 383, at 6, and thus were not "sufficiently dramatic" to put her on notice. *Id.* at 9.

There are several flaws with that argument. As an initial matter, pelvic pain caused by "mesh erosion" is the very condition that is the premise of this lawsuit. Plaintiff's own theory is that Coloplast's mesh device is defectively designed because the "side effect" (or adverse event) of "mesh erosion" occurs so frequently that the risks of the product outweigh its benefits. *See supra*, 9, 11-12. There is no distinction between a mesh erosion occurring as a "common side effect of the surgery" and a mesh erosion occurring as a result of an alleged design defect. Plaintiff's defect theory is simply that the "common side effect" of mesh erosion is *too common*. With that premise in mind, the accrual of Plaintiff's claim was not delayed even if she reasonably believed that mesh erosion is a common side effect of mesh implant surgery. Knowledge of mesh erosion is still the trigger for a lawsuit about mesh erosion, especially when coupled with knowledge that "something was wrong" with the mesh product.

More fundamentally, Plaintiff's argument that her symptoms needed to be "sufficiently dramatic" to provide her notice confuses two lines of Florida precedent: "undiagnosed cases" and "diagnosed cases." When a plaintiff hasn't yet been told that a product caused her injury, she is not on notice unless her injury is "distinct in some way from conditions naturally to be expected from the plaintiff's condition." *Babush v. Am. Home Prod. Corp.*, 589 So. 2d 1379, 1381 (Fla. Dist. Ct. App. 1991). Accordingly, some symptoms do not, in and of themselves, provide a plaintiff with sufficient notice as a matter of law. Examples from medical malpractice cases include a patient experiencing pain post-surgery, *Gonzalez v. Tracy*, 994 So. 2d 402, 405 (Fla. Dist. Ct. App. 2008), or a child developing cerebral palsy after delivery, *Mobley v. Homestead Hosp., Inc.*, 291 So. 3d 987, 991–92 (Fla. Dist. Ct. App. 2019). But some symptoms, like going blind after a routine colon operation, are so clearly the result of negligence that they put a plaintiff on notice as a matter of law. *Barron v. Shapiro*, 565 So. 2d 1319, 1321 (Fla. 1990), *holding modified by Tanner v. Hartog*, 618 So. 2d 177 (Fla. 1993).

But this dichotomy does *not* apply to "diagnosed cases" like this one, where Plaintiff was *told* that a product (mesh) caused her injury ("mesh

erosion") and understood that something was wrong with the product. Florida courts have consistently held that actual knowledge of the cause of an injury triggers the statute of limitations. *Brown & Williamson*, 778 So. 2d at 934; *Spiewak*, 73 So. 3d at 127; *Bogorff*, 583 So. 2d at 1004. Where a plaintiff already knows what caused her injury, it would make no sense to require that her injury *also* be distinct enough to independently put her on notice.

II. Alternatively, This Court Should Certify The Question To The Florida Supreme Court

If this Court is uncertain as to whether Plaintiff's claim is time-barred as a matter of law, it should certify the following question to the Florida Supreme Court:

> In a product-liability lawsuit alleging that a defectively designed mesh device eroded and thereby caused pelvic pain, does Florida Statute § 95.031(2)(b) begin to accrue as a matter of law when the plaintiff is diagnosed with an erosion of the mesh causing pelvic pain, and the plaintiff also knows that "something was wrong" with the mesh device?[3]

[3] Of course, neither the presentation of the issue nor the phrasing of the question are meant to be binding on this Court or the Florida Supreme Court. *Salinas v. Ramsey*, 858 F.3d 1360 (11th Cir. 2017), *certified question answered*, 234 So. 3d 569 (Fla. 2018).

Certification is appropriate where "[t]he questions presented are [A] sufficiently unsettled, [B] important, and [C] likely to recur." *In re Cassell*, 688 F.3d 1291, 1292 (11th Cir. 2012), *certified question answered sub nom. Silliman v. Cassell*, 292 Ga. 464, 738 S.E.2d 606 (2013).

A. If the question presented is not clear in Coloplast's favor, then it is at least unsettled

As already explained, several Florida cases indicate that a diagnosis that links the injury to the product, along with the plaintiff's knowledge that "something was wrong with the product," easily triggers Florida's statute of limitations. *See, e.g.*, *Brown & Williamson*, 778 So. 2d at 934; *Spiewak*, 73 So. 3d at 127; *Bogorff*, 583 So. 2d at 1004. If, however, the Court is left with any doubt about whether Florida law is clear on this point, it should at least conclude that Florida law is unsettled. No Florida appellate court has had a chance to weigh in on the application of the statute of limitations in a pelvic mesh case, and no Florida appellate court has adopted the legal positions regarding the statute of limitations advanced by Plaintiff here. If this Court were to consider adopting those positions, federalism and comity dictate that a Florida court, and not the federal courts, should have first say.

At least two of Plaintiff's arguments represent significant departures from established Florida law that should not be adopted without the Florida Supreme Court's input. First, the district court imposed a "distinct injury" requirement in this case based on its reading of *Eghnayem*. But the Florida Supreme Court has never imposed such a requirement in a product-liability case, much less in a case where a plaintiff has been told of the source of her injury. As explained *supra* at 37-38, where a plaintiff already knows what caused her injury, it would make no sense to require that her injury *also* be distinct enough to independently put her on notice.

The district court adopted the "distinct injury" language from *Eghnayem*, 873 F.3d at 1323, which in turn got it from *Babush v. Am. Home Prod. Corp.*, 589 So. 2d 1379, 1381 (Fla. Dist. Ct. App. 1991), a case that did *not* involve a diagnosis with a link to the product, *see id.* at 1380 ("There is no evidence that any correlation between the drug and the disease was mentioned in connection with the diagnosis."). *Babush* also antecedes the Florida Supreme Court's ruling in *Brown & Williamson*, which imposed no "distinct injury" requirement and only required "some evidence of causal connection" between injury and the product" for the

claim to accrue. 778 So.2d at 934. The Florida Supreme Court should decide whether an additional "distinct injury" requirement exists in product liability cases where the plaintiff received a diagnosis that links the injury to the product.

Second, Plaintiff has argued that knowledge of a product defect is required to start the limitations period. As discussed earlier, the Florida Supreme Court has never imposed such a requirement in any of its product liability cases. *See, e.g.*, *Brown & Williamson*, 778 So. 2d at 934; *Spiewak*, 73 So. 3d at 127; *Bogorff*, 583 So. 2d at 1004. But, in fairness, the Supreme Court has required something similar in the context of medical malpractice cases, holding in *Tanner v. Hartog*, 618 So. 2d 177 (Fla. 1993), that the defendant must prove the plaintiff's actual or constructive knowledge of "a reasonable possibility that the injury was caused by medical malpractice." *Id.* at 181.

There is serious doubt whether the Florida Supreme Court would take the same approach in a product liability case, as the relevant policy considerations are different. For decades, Florida's "*Nardone* rule" dictated that in a medical malpractice suit, "the statute of limitations commences *either* when the plaintiff has notice of the negligent act giving

rise to the cause of action *or* when the plaintiff has notice of the physical injury which is the consequence." *Nardone v. Reynolds*, 333 So. 2d 25, 32 (Fla. 1976) (emphases added). Under that rule, a plaintiff could not bring a medical malpractice action more than two years after they were harmed, even if they had no reason to know their injury was caused by medical negligence. *See Bogorff*, 583 So. 2d at 1002.

That rule changed in *Tanner*. There, the Florida Supreme Court noted that strict application of the *Nardone* rule "may not produce just or even reasonable results," particularly where a patient's injury may be "a result of natural causes rather than . . . medical negligence." *Id.* at 181. In those circumstances, "[t]he *Nardone* rule tend[ed] to put a strain on the doctor-patient relationship because whenever something bad happens in the course of medical treatment, the patient must make an early investigation of the possibility of malpractice." *Id.* In light of those unique concerns, the *Tanner* court crafted a new rule for medical malpractice actions: "the knowledge of the injury as referred to in the rule as triggering the statute of limitations means not only knowledge of the injury but also knowledge that there is a reasonable possibility that the injury was caused by medical malpractice." *Id.*

Importantly, the Florida Supreme Court has given no indication that the more lenient rule from *Tanner* applies in the product-liability context. Given that the *Tanner* rule was motivated by the unique doctor-patient relationship, it should not be casually assumed that the Florida Supreme Court would superimpose that rule onto the product-liability context. To Coloplast's knowledge, *Bogorff* is the only case where the Florida Supreme Court has considered a medical malpractice claim alongside a product-liability claim, *see* 583 So. 2d at 1001, and there the court sequestered its analysis, considering each claim separately. *Id.* at 1004. There was no indication in *Bogorff* that medical malpractice and product liability caselaw are interchangeable.

And in *Brown & Williamson*, the first product-liability case decided after *Tanner*, the Florida Supreme Court merely required "some evidence of causal connection" of the injury to the product for the claim to accrue—*not* knowledge of a product defect. 778 So. 2d at 934. If knowledge of the defect were required for the claim to accrue, the Supreme Court would have said so.

At the very least, it is "sufficiently unsettled" that the Florida Supreme Court would apply the district court's approach to Plaintiff's

product liability claim. *In re Cassell*, 688 F.3d at 1292. If this Court were to consider adopting these novel expansions, then certification would "promot[e] the interests of cooperative federalism [and] help[ ] save time, energy, and resources." *King v. King*, 46 F.4th 1259, 1267 (11th Cir. 2022) (citation omitted) (cleaned up).

B. The question presented is important

"Statutes of limitations are not simply technicalities. On the contrary, they have long been respected as fundamental to a well-ordered judicial system." *Bd. of Regents of Univ. of State of N.Y. v. Tomanio*, 446 U.S. 478, 487 (1980). In passing section 95.031(2)(b), the Florida Legislature decided that a delay of more than four years "is sufficiently likely to either impair the accuracy of the fact-finding process or to upset settled expectations that a substantive claim will be barred." *Id.* That determination undergirds "important policy considerations," including promoting settlement and reducing uncertainty. *Allstate Ins. Co. v. Metro. Dade Cnty.*, 436 So. 2d 976, 980 (Fla. Dist. Ct. App. 1983).

Here, the district court held that a plaintiff's actual knowledge that a defective product harmed her, along with awareness that something was wrong with the product, is not sufficient to trigger the statute of

limitations. Legal merits aside, that decision has the potential to significantly increase the cost of medical products for ordinary Floridians, who will have to subsidize the cost of a longer statute of limitations. That policy decision is best made by the Florida judiciary—not a federal court.

C. The question presented is likely to recur

Product-liability suits, including pelvic mesh cases, constitute a hefty portion of a federal court's docket. Thousands of mesh cases, along with other medical device cases, remain pending in the federal courts, including hundreds in Florida alone. Without certification, federal courts will continue to make *Erie* guess after *Erie* guess, with each incorrect guess compounding the effects of the decision before it.

In fact, federal district courts have already reached diverging results in Florida medical device cases. *Compare Sotolongo v. Ethicon, Inc.*, 591 F. Supp. 3d 1242 (S.D. Fla. 2022) (holding that a vaginal mesh claim was time-barred where plaintiff was diagnosed with mesh erosion more than four years earlier), *with Boneta v. Am. Med. Sys., Inc.*, 524 F. Supp. 3d 1304, 1312–15 (S.D. Fla. 2021) (holding, under *Eghnayem*, the claim did not even accrue upon first mesh revision surgery), *and Pirlein*

v. Ethicon, Inc., No. 20-62202-CIV, 2021 WL 4990612, at *3–5 (S.D. Fla. Oct. 1, 2021) (similar).

In sum, while certification is not required because Florida law is clear that Plaintiff's claim is time-barred, if this Court has any doubt on that score, then it should let the Florida Supreme Court do what it does best—decide questions of Florida law.

CONCLUSION

This Court should reverse and remand with instructions to enter judgment for Coloplast. Alternatively, this Court should certify the issue to the Florida Supreme Court.

Respectfully submitted,

s/Val Leppert

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January 6, 2023

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 9,487 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Century Schoolbook size 14-point font with Microsoft Word 365Plus.

Date: January 6, 2023

s/*Val Leppert*
Val Leppert

Counsel for Coloplast Corp.

CERTIFICATE OF SERVICE

I hereby certify that on January 6, 2023, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Eleventh Circuit by using the CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

s/*Val Leppert*
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